MAY 10 2013

Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K121719
Date:	October 23rd, 2012
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Hong Qiangxing (Shen Zhen) Electronics Limited 4F, Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen City, Guangdong, China 518126
Contactor:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add.: Room 1706 Yuesha, No. 128 Songle Rd., Songjiang, Shanghai, China 201600 E-mail: doris_d@126.com Tel: 86 21-31261348 Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	SM TENS & PMS
Common Name:	TENS & PMS
Classification Name:	Stimulator, nerve, transcutaneous, over-the-counter, Stimulator, muscle, powered, for muscle conditioning
Regulation Number:	882.5890, 890.5850
Product Code:	NUH, NGX
Device Class:	II
Review Panel:	Neurology & Physical Medicine
Device Description:	SM TENS & PMS is a portable and DC 3.7V battery powered multi function device, offering both Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities in one device. SM TENS & PMS has 6 operation modes, which can give certain electrical pulses through electrode adhesive pads to the suggested area of the body where the electrodes are placed. The electronic stimulatory module has the operating elements of ON/OFF Switch, Display screen, Mode Selection key, Intensity Modification keys, Timing key, Pause key, Output socket, and USB port for battery charging. The display screen can show battery power, selected mode, current intensity, time remaining of an application mode, and indication of a pause. The device is equipped with accessories of electrode pads, electrode cables, battery chargers, and USB cables. The electrode cables are used to connect the pads to the device; the USB cable is used to connect the charger and the built-in lithium battery. All accessories, including USB cables, electrode pads, electrode cables, chargers can only be changed by special

person.

The electrodes are interchangeable. The application area of electrode pads must be larger than 4cm^2. The electrode pads are provided by GMDASZ Manufacturing Co., Ltd. with 510(k) cleared Number K092546.

Indications for use:

TENS:

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

PMS:

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

3. Substantial Equivalence to Predicate device:

Detailed comparison data is included in "Section 9 - Substantial Equivalence Discussion" of this 510(k) submission.

Parameters		New Device	Predicate Device
1.	510(k) Number	K121719	K102598
2.	Marketing clearance date:	--	May 13, 2011
3.	Device Name	SM TENS & PMS	Powered Muscle Stimulator, JQ-5C
4.	Manufacturer	Hong Qiangxing (Shenzhen) Electronics Limited	Hi-Dow International, Inc.
5.	Accessories	Self-adhesive electrodes, electrode wires, Battery charger, USB cable	Self-adhesive electrodes, electrode wires, Battery charger, USB cable
6.	Intended use	TENS (Mode 1, 3, 4, 5, 6): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Mode 1, 2, 3, 6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS (Mode 1, 3, 4, 5, 6): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. PMS (Mode 1, 2, 3, 6): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.
7.	Power Source(s)	DC 3.7V lithium battery	DC 3.7V lithium battery
	- Method of Line Current Isolation	Type BF	Type BF
	- Patient Leakage Current - Normal Condition - Single Fault Condition	-- 2μA < 10μA	-- 2μA < 10μA
8.	Average DC current through electrodes when	< 0.01μA	< 0.01μA

	device is on but no pulses are being applied (μA)		
9.	Number of Output Modes	6	6
10.	Number of Output channels:	2	2
	- Synchronous or Alternating?	Synchronous	Synchronous
	- Method of Channel Isolation	Voltage transformer Isolation	Voltage transformer Isolation
11.	Timer Range (minutes)	10 ~ 60 minutes, 10 min./step	10 ~ 60 minutes, 10 min./step
12.	Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, FCC 47 CFR Part 18	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10
13.	Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
14.	Shape	Rectangular, with interphase interval,	Rectangular, with interphase interval
15.	Maximum Output Voltage (volts)	42V±10% @500Ω	62.4V @500Ω
		84V±10% @2kΩ	76V @2kΩ
		130V±10% @10kΩ	84V @10kΩ
16.	Maximum Output Current (specify units)	84mA±10% @500Ω	124.8mA @500Ω
		42mA±10% @2kΩ	38mA @2kΩ
		13mA±10% @10kΩ	8.4mA @10kΩ
17.	Pulse width (μsec)	100μs	100μs
18.	Max. pulse frequency (Hz)	110Hz	61.3Hz
19.	Net Charge (μC per pulse)	0μC @500Ω; Method: Balanced waveform	0μC @500Ω; Method: Balanced waveform
20.	Maximum Phase Charge, (μC)	16.8μC @500Ω	17.92μC @500Ω
21.	Maximum Average Current, (mA)	0.924mA @500Ω	1.248mA @500Ω
22.	Maximum Current Density, (mA/cm², r.m.s)	0.462mA/cm² @500Ω	9.92mA/cm² @500Ω
23.	Maximum Average Power Density, (W/cm²)	9.702mW/cm² @500Ω	2.72mW/cm²@500Ω
Similarities between New device and Predicate Device:		Same intended use, power supply, components, 6 modes, 2 channels, software controlled, standards, same waveform and wave shape, same pulse width, net charge, similar phase charge and maximum average current	
Differences between New device and Predicate Device:		Different weight and dimensions, different values of Maximum Average Power Density because of different smallest surface area of electrodes; The new device provides safety test report on battery	
Conclusion:		The SM TENS & PMS is substantially equivalent to the Powered Muscle Stimulator, JQ-5C (K102598). This conclusion is based upon comparison on design, technical characteristics, output mode, intended use, and safety standards complied with. Any differences in the technological characteristics do not raise any new safety and effectiveness issues.	

4. Safety and Effectiveness of the device:

SM TENS & PMS is safe and effective as the predicate devices cited above.

The new device has passed testing according to the safety standards:

1) IEC 60601-1: 2005, Medical Electrical Equipment - Part 1: General Requirements for Safety
2) IEC 60601-2-10: 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators;
3) IEC 60601-1-2: 2001, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests;
4) IEC 62133: 2002, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
5) FCC 47 CFR Part 18 Telecommunication: Industrial, Scientific, and Medical Equipment; Conducted Emissions

The conclusion drawn from the safety testing is that the new device is substantially equivalent to the predicate device. Furthermore, the new device complies with the recognized standards and performs its intended tasks as well as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2013

Hong Qiangxing (Shen Zhen) Electronics Limited
% Shanghai CV Technology Co., Ltd.
Attn: Ms. Doris Dong
Room 1706 Yuesha, No. 128 Songle Rd., Songjiang Area
Shanghai, 201600 China

Re: K121719
Trade/Device Name: SM TENS & PMS
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH
Dated: April 24, 2013
Received: May 1, 2013

Dear Ms. Dong:

This letter corrects our substantially equivalent letter of May 10, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4
Indications for Use Statement

510(k) Number (if known): K121719

Device Name: SM TENS & PMS

Indications for Use:

TENS:

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.

PMS:

It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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